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Atty. Dkt. No. 034827-9103

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Caulfield, et al.
Title: DETERMINATION OF
TESTOSTERONE BY MASS
SPECTROMETRY
Appl. No.: 10/726,919
Filing Date: 12/02/2003
Examiner: Unknown
Art Unit: 1645

<p>CERTIFICATE OF MAILING I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as First Class Mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on the date below.</p> <p><u>DIANE GARCIA</u> (Printed Name)</p> <p><u>[Signature]</u> (Signature)</p> <p><u>5-27-04</u> (Date of Deposit)</p>

INFORMATION DISCLOSURE STATEMENT
UNDER 37 CFR §1.56

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Submitted herewith on Form PTO/SB/08 is a listing of documents known to Applicants in order to comply with Applicants' duty of disclosure pursuant to 37 CFR §1.56. A copy of each listed document, except as noted below, is being submitted to comply with the provisions of 37 CFR §1.97 and §1.98.

The USPTO has waived the requirement under 37 CFR 1.98(a)(2)(i) to submit copies of U.S. patents and U.S. patent application publications when citing and submitting an Information Disclosure Statements in a patent application filed after June 30, 2003 and in an international application that has entered the national stage under 37 USC §371 after June 30, 2003. Accordingly, copies of these types of documents are not being supplied in connection with this application. Reference is being made to Pre-OG Notice from Office of Patent Legal Administration dated July 25, 2003, *Information Disclosure Statements May Be Filed Without*

Copies of U.S. Patents and Published Applications in Patent Applications filed after June 30, 2003.

The submission of any document herewith, which is not a statutory bar, is not intended as an admission that such document constitutes prior art against the claims of the present application or that such document is considered material to patentability as defined in 37 CFR §1.56(b). Applicants do not waive any rights to take any action which would be appropriate to antedate or otherwise remove as a competent reference any document which is determined to be a *prima facie* art reference against the claims of the present application.

TIMING OF THE DISCLOSURE

The listed documents are being submitted in compliance with 37 CFR §1.97(b), before the mailing date of the first Office Action on the merits.

RELEVANCE OF EACH DOCUMENT

All of the documents are in English.

Applicants respectfully request that any listed document be considered by the Examiner and be made of record in the present application and that an initialed copy of Form PTO/SB/08 be returned in accordance with MPEP §609.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 CFR §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 50-0872. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 50-0872.

Respectfully submitted,

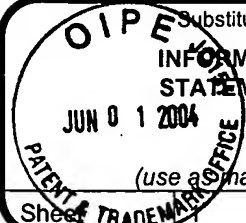
Date 5/26/04

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Registration No. 39,431

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 Substitute for form 1449B/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)		Complete if Known	
		Application Number	10/726,919
		Filing Date	12/02/2003
		First Named Inventor	Michael P. Caulfield
		Group Art Unit	1645
		Examiner Name	Unknown
Sheet <u>1</u> of <u>3</u>		Attorney Docket Number	034827-9103

U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number	Kind Code ² (if known)			
	A1	5772874		Quinn et al.	06-30-1998	
	A2	5795469		Quinn et al.	08-18-1998	
	A3	5919368		Quinn et al.	07-06-1999	
	A4	5968367		Quinn et al.	10-19-1999	
	A5	6107623		Bateman et al.	80-22-2000	
	A6	6124137		Hutchins et al.	09-26-2000	
	A7	6204500		Whitehouse et al.	03-20-2001	
	A8	6268144		Koster	07-31-2001	

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Foreign Patent Document			Name of Patentee or Applicant of Cited Documents	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁶
		Office ³	Number ⁴	Kind Code ⁵ (if known)				

NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ⁶
	A9	Carignan et al., "High-performance liquid chromatographic analysis of estradiol valerate-testosterone enanthate in oily formulations" <i>J Chrom</i> 301(1):292-96 (1984)	
	A10	Choi et al., "Rapid HPLC-Electrospray Tandem Mass Spectrometric Assay for Urinary Testosterone and Dihydrotestosterone Glucuronides from Patients with Benign Prostate Hyperplasia." <i>Clin. Chem.</i> 49: 322-5 (2003)	
	A11	Choi et al., "Determination of Four Anabolic Steroid Metabolites by Gas Chromatography/Mass Spectrometry with Negative Ion Chemical Ionization and Tandem Mass Spectrometry" <i>Rapid Commun. Mass Spectrom</i> 12, 1749-55 (1998)	
	A12	Dorgan et al., "Measurement of steroid sex hormones in serum: a comparison of radioimmunoassay and mass spectrometry." <i>Steroids</i> 67: 151-8 (2002)	

Examiner Signature		Date Considered	
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*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number. ² See attached Kinds of U.S. Patent Documents. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

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Sheet	2	of	3		

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	A13	Furuta et al., "Simultaneous Measurements of Endogenous and Deuterium-Labelled Tracer Variants of Androstenedione and Testosterone by Capillary Gas Chromatography-Mass Spectrometry." <i>J Chrom, Biomed Appl</i> Vol. 525: 15-23, (1990)	
	A14	Giraudi et al., "Effect of Tracer Binding to Serum Proteins on the Reliability of a Direct Free Testosterone Assay." <i>Steroids</i> 52: 423-4 (1988)	
	A15	Marcus and Durnford, "A Simple Enzyme-Linked Immunosorbent Assay for Testosterone." <i>Steroids</i> 46: 975-86 (1985)	
	A16	Merchant and Weinberger, "Recent advancements in surface-enhanced laser desorption/ionization-time of flight-mass spectrometry." <i>Electrophoresis</i> 21: 1164-67 (2000)	
	A17	Minut et al., "Urinary 5 α -androstenediol and 5 β -androstenediol measurement by gas chromatography after solid-phase extraction and high-performance liquid chromatography." <i>Int'l J Biol. Markers</i> , Vol. 14(3); 154-59 (1999)	
	A18	Ooi and Donnelly, "More on the Analog Free-Testosterone Assay." <i>Clin. Chem.</i> 45: 714-715 (1999).	
	A19	Robb et al., "Atmospheric pressure photoionization: An ionization method for liquid chromatography-mass spectrometry." <i>Anal. Chem.</i> 72(15): 3653-3659 (2000).	
	A20	Winters et al., "The analog free testosterone assay: are the results in men clinically useful?" <i>Clin. Chem.</i> 44:2178-2182, (1998).	
	A21	Wright et al., "Proteinchip surface enhanced laser desorption/ionization (SELDI) mass spectrometry: a novel protein biochip technology for detection of prostate cancer biomarkers in complex protein mixtures." <i>Prostate Cancer and Prostatic Diseases</i> 2: 264-76 (1999)	

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	A22	Zimmer <i>et al.</i> , "Comparison of turbulent-flow chromatography with automated solid-phase extraction in 96-well plates and liquid-liquid extraction used as plasma sample preparation techniques for liquid chromatography-tandem mass spectrometry." <i>J. Chromatogr. A</i> 854: 23-35 (1999)	

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